**Report in Brief**
Date: June 2019
Report No. A-03-16-00354

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

# The Food and Drug Administration Generally Complied With Federal Requirements for the Preparation and Receipt of Select Agent Shipments

## Why OIG Did This Review

The Food and Drug Administration (FDA) is one of several Federal agencies that ship and receive select agents. Select agents are biological agents or toxins that HHS and the Department of Agriculture have determined pose a threat to humans, animals, plants, or the environment. In 2015, another Federal agency found that one of its facilities had inadvertently shipped live *Bacillus anthracis*, a select agent which causes the deadly disease anthrax, to 194 laboratories in the United States and other countries. In response to these events, we initiated a review of the policies, procedures, and protocols FDA implemented to ensure the safe shipment of select agents to and from its laboratories.

Our objective was to determine whether FDA has designed and put in place controls to ensure that select agent shipments are prepared and received in accordance with Federal regulations and related supporting laboratory guidance and instruction.

## How OIG Did This Review

We reviewed eight select agent shipments either sent or received by one of FDA's 11 registered entities from October 1, 2013, through September 30, 2015. We also requested documentation of all inactivated select agents shipped and received during the same period. We reviewed relevant FDA policies, training documentation, and inactivations for compliance with Federal requirements and guidance.

## What OIG Found

Generally, FDA has designed and put in place controls to ensure that select agent shipments are prepared and received in accordance with Federal regulations and related supporting laboratory guidance and instruction. However, 8 of FDA's 11 registered entities' security plans did not include certain procedures for notifying the Federal Select Agent Program (FSAP) if a select agent shipment is not received within 48 hours after the expected delivery time or a select agent shipment receives damage to the extent that a select agent release may have occurred, and none of FDA's registered entities' security plans included certain procedures for notifying FSAP if an authorization for a select agent transfer expires or becomes void before the shipment is completed. In addition, we found that FDA's registered entities did not always maintain required select agent training documentation and did not have sufficient policies to ensure compliance with all new requirements for shipping select agents that have undergone inactivation.

## What OIG Recommends and FDA Comments

We recommend that FDA update its registered entities' security plans to include procedures for notifying FSAP if a select agent (1) shipment is not received within 48 hours after the expected time of delivery, (2) package is received damaged to the extent that a release of the select agent may have occurred, (3) shipment will not be completed within 30 calendar days after transfer authorization issuance, or (4) transfer authorization becomes void because the facts supporting the authorization changed. We also made recommendations regarding FDA's select agent training documentation and policies for shipping inactivated select agents.

In written comments on our draft report, FDA concurred with our recommendations and stated that it has taken actions to implement them. FDA indicated that it has developed a standardized template for the Select Agent Security Plan used by the Office of Regulatory Affairs and FDA Centers that participate in FSAP that addresses all of our recommendations. FDA also stated that it has revised its policies to address all of the recommendations. Finally, FDA provided technical comments on our draft report that we have addressed in this report as appropriate.